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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,797	06/12/2002	Herman Jan Tijmen Coelingh Bennink	97473 US	8680

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07/15/2003

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/15/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,797

Applicant(s)

COELINGH BENNINK ET AL.

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 4-18 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4,10-14 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group III, claims 2,4 and 10-14 and 16-18, drawn to a method of anti-progestagen therapy comprising administering the anti-progestagen of Formula II in Paper No. 8 is acknowledged. It is noted that claim 15 was inadvertently included in Group III but it should have been included in Group II since claim 15 depends on claim 8. Upon reconsideration, the restriction set forth on the last Office Action is modified to examine claims 5 and 6 with the related Groups I or II, not with the elected Group III, since they lack special technical feature as posing different activity (combination of unrelated compounds e.g. agonist vs. Antagonist). It is noted that claims 5 and 6 are directed to a combined dosage unit comprising a progestagen and an anti-progestagen, which is related to invention of Groups I or II.

Applicants' traversal is on the ground(s) that claims 7 and 9, drawn to methods of contraception, should be included in Group III drawn to methods of anti-progestagen therapy as well and similarly, claim 8 should be included as it is also a method of anti-progestagen therapy. This is not found persuasive because the claims 7-9 are drawn to different method employing a combination of unrelated compounds for the treatment of unrelated medical disorders or conditions have different known etiology and have different known treatment. The unrelated compounds have different known effects and different physical and chemical properties. The inventions of Groups I or II would

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support a separate patent for the elected invention. Therefore, the restriction requirement of last Office Action is deemed proper.

Accordingly, claims 5-9 and 15 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "each pair" is indefinite since it is not clear which active agents make "pair". Is it referred to two of the same anti-progestgens administered or is it referred to one of anti-progestagen dose with other active agents?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 4, 10-14 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodgen (WO 93/21927) of record in view of Schoonen et al. (XP-002124156) of record and Hamersma et al. (U.S. Patent No. 5,854,235).

Hodgen teaches a method for minimizing menstrual bleeding irregularities in individuals using progestin-only pharmaceutical preparation, such as contraceptive, comprising administering anti-progesterone such as Org 31710. (abstract, page 5, lines 20-30, page 7, lines 20-32). Hodgen teaches that anti-porgestin above can be administered monthly, or at other intermittent intervals. (page 9, lines 32-36). Hodgen teaches the intervals and number of doses can vary and a suitable regimen is having the anti-progestin administered every thirty days, every sixty days or every ninety days and in the case of contraceptives, the anti-progestin can be administered on the twenty-eighth day of each cycle. (page 10, lines 5-20).

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Schoonen teaches the anti-progestinic activity of Org 33245 is compared to that of Org 31710, in vitro and in vivo, it is shown that the Org 33245 is more active than the Org 31710. (abstract, page 164, table, right hand column, lines 18-24, page 167, right-hand column, lines 1-7).

Hamersma et al. teach that Org 33245 is useful in contraception and it exhibit the normal activities known for anti-progestogen such as treatment of menstrual disorders and hormone dependent tumors. (column 1, lines 1-8, column 12, lines 33-36).

The differences between Hodgen and Applicants' claims are the employment of specified anti-progestagen, Org 33245 and the specific dosing schedule set forth in claim 4.

It would have been obvious to one of ordinary skill in the art to modify Hodgen's method to employ Org 33245 in place of Org 31710 because Schoonen teaches Org 33245 is compared to that of Org 31710, in vitro and in vivo, it is shown that the Org 33245 is more active than the Org 31710 and because Hemersma et al. teach that Org 33245 is exhibits the normal activities known for anti-progestogen such as treatment of menstrual disorder and useful for contraception.

One of ordinary skill in the art would have been motivated to modify Hodgen's method to employ Org 33245 in place of Org 31710 to achieve expected benefit of increased activity of anti-progestin therapy for the contraception and decreased in menstrual disorder such as bleeding. Absent any evidence to contrary, there would have been reasonable expectation of successfully employing Org 33245 in Hodgen's method in hormone replacement therapy, e.g. contraception and bleeding irregularities.

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The dosing schedule set forth in claim 4 is obvious because the intervals can vary with concurrent medication therapy and each optimum dosing frequency are determined by the practitioners; further 1-7 days during a cycle of 28-32 day administration is obvious since they are all within the conventional dosing regimen of contraceptives.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

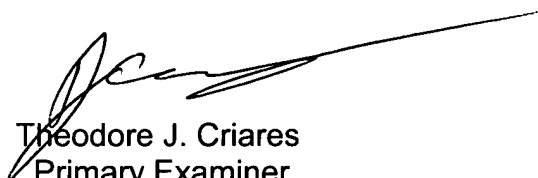
None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Theodore J. Criares
Primary Examiner
Art Unit 1617

jmk
July 14, 2003